Remarks

This Amendment is in response to the Office Action dated **August 6, 2010.**

Rejections – 35 U.S.C. §102(e)

Claim 65 has been rejected under 35 U.S.C. §102(e) as being anticipated by Steadham et al. (USPN 7,331,933). It is asserted in the Office Action that "Steadham et al. discloses a balloon with compression member."

Applicants disagree and traverse the rejection.

Applicants submit that Steadham et al. disclose compression members which are which contract from a first diameter to a smaller diameter to sealing secure the balloon to an outer tubular member and an inner tubular member of a catheter shaft.

Applicants submit that there is nothing in the disclosure of Steadham et al. to suggest that the compression bands disclosed therein in their rest configuration have a smaller diameter than the balloon body over which they are disposed.

Steadham discloses the following materials for forming the compression members:

> A variety of suitable materials can be used to form the compression member of the invention including composite materials such as platinum-iridium, gold based alloys, stainless steel, platinum alloys, cobalt-chromium alloys, carbon fibers, polymeric materials such as nylon, polyamides, polyethelenes, polymides, polyester, shrink tubing or FEP, shape memory or superelastic materials such as nitinol, and radiopaque metals such as gold or tungsten, as wells as those materials previously mentioned. In addition to securing the balloon to the shaft, the compression members made from radiopaque materials are visible under fluoroscopy and thus can indicate the position of the balloon in a patient.

Steadham et al. does not, however, suggest that any of these materials are contracted to have an at rest diameter which is smaller than that of the balloon over which they

are disposed.

Shrink tubing is a term of art employed to describe materials which have a stable configuration at ambient temperature but shrink when heated. However, also with respect to this material, there is nothing in the disclosure of Steadham et al. to suggest that it would shrink to a diameter that is smaller than the balloon body over which it is applied in an at rest configuration.

Steadham et al. fails to anticipate claim 65 because Steadham et al. fails to disclose or suggest all of the elements of the claimed invention as set forth in the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131.

Withdrawal of the rejection of claim 65 under 35 U.S.C. §102(e) as being anticipated by Steadham et al. is respectfully requested.

Rejections – 35 U.S.C. §103(a)

I. Anderson in view of Yang et al.

Claims 27-28 and 63-64 have been rejected under 36 U.S.C §103(a) as being obvious over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796).

Applicants traverse the rejection.

Independent claims 27 and 63 are directed to embodiments wherein a medical balloon is formed from a radiation curable composition and has a lumen which extends through the tapered ends of the balloon and is offset from the longitudinal axis of the balloon. Other features are recited.

It is alleged in the Office Action that Anderson discloses all of the features of the claimed invention, but for specific balloon materials for which Yang et al. is employed. "However, Yang et al. teaches a hydrophilic lubricity coating. Regarding claims 27-28 and 63-64, Yang et al. teaches a balloon catheter (10, Figure 2) wherein the balloon formed of radiation cured polymerized composition ([0053])." Office Action, bottom of page 4.

This is incorrect.

Yang et al. discloses, paragraph [0053}, the following:

> [0053] A catheter useful for angioplasty having a balloon with a 3.0 mm diameter and a length of 20 mm was used in this example. The balloon was coated with a high molecular weight polyethylene oxide coating which had a 2,2'-azobis isobutyro-nitrile catalyst (both from Aldrich Chemical). The coating was subsequently dried and cured under UV radiation to facilitate crosslinking of the polyethylene oxide.

The balloons disclosed by Yang et al. are actually formed from a variety of thermoplastic polymer materials:

> [0019] Very little limitation is placed on the material for the elongate body 41. Most devices will have a relatively flexible body, such as when the device 40 is a catheter or guide wire. However, the invention may also be used with inflexible transcutaneous devices such as a needle. Body 41 may be made of organic high polymer materials such as polyamide, polyester, polyvinyl chloride, polystyrene, polyacrylate, polymethacrylate, polyacrylonitrile, polyacrylamide, polyethylene, polypropylene, polyurethane, polyvinyl acetate, silicone resins and copolymers and blends thereof. However, various inorganic materials such as glass, ceramic, stainless steel, and super elastic metal or shape memory alloy such as Ni--Ti, and the like may be employed on part or all of body 41. Body 41 may also be formed as a composite of different materials which are laminated together. Depending on the nature of the specific device 40, body 41 may be provided with one or more lumens, electrical connectors, optical fibers or the like, as is well known in the medical art.

Yang et al. fails to disclose or suggest forming the balloon itself from a radiation curable composition.

As the combination fails to disclose or suggest all of the elements recited in

independent claims 27 and 63, namely a balloon formed from a radiation curable composition, no *prima facie* showing of obviousness has been established. "[T]he prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP 2143.

Claims 28 and 64 depend from claims 27 and 63 respectively and are not obvious over Anderson in view of Yang et al. for at least these reasons.

Withdrawal of the rejection of claims 27-28 and 63-64 under 36 U.S.C §103(a) as being obvious over Anderson (USPN6,007,517) in view of Yang et al. (US2001/0003796) is respectfully requested.

II. Steadham et al. in view of Crocker et al.

Claims 66-68 have been rejected under 35 U.S.C. §103(a) as being obvious over Steadham et al. (USPN 7,331,933) in view of Crocker et al. (USPN 6,120,523).

Applicants traverse the rejection.

Claims 66-68 depend from claim 65 which has been discussed above.

Steadham et al. fail to disclose or suggest that the compression bands disclosed therein contract to a smaller diameter than the balloon over which they are disposed.

It is asserted in the Office Action that:

> Steadham meets the claim limitations as described above except for the bands being located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition.
> However, Crocker et al. teaches a focalized intraluminal balloon.
> Regarding claims 66-68, Crocker et al. teaches a polymeric (cross-linked

> polyethylene, col 7, In 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change.
>
> At the time of the invention, it would have been obvious to change the placement of the bands and the balloon materials of Steadham in order to gain additional balloon inflation control properties.
>
> Office Action, page 5

However, Crocker et al. like Steadham et al., fail to disclose or suggest that the expansion limiting bands are stretched over the balloon and have an at rest configuration wherein the diameter is less than that of the balloon over which they are disposed. In fact, Crocker et al. disclose that the materials are non-distensible, an indication that they can neither be stretched nor would contract, a conclusion consistent with the materials recited for use therein. See column 5, lines 24-43.

> In the illustrated embodiment, an inner balloon **36** is disposed coaxially within an outer balloon **38**. A substantially nondistensible expansion limiting band **40** is disposed in between the balloons **36** and **38** adjacent a proximal annular shoulder **42**, to limit the radial expansion of the balloon **18**. Similarly, a distal expansion limiting band **44** is disposed between the inner balloon **36** and outer balloon **38** adjacent a distal annular shoulder **46**.
>
> Expansion limiting bands **40** and **44** or other inflation limiting structures can be provided in any of a variety of ways which will be well-understood by one of skill in the art in view of the disclosure herein. For example, in one embodiment, the bands **40** and **44** each comprise a tubular section of polyester, each having an axial length of about 5 mm, a diameter of about 2.5 mm and a wall thickness of about 0.0003 inches. Other generally nondistensible materials such as nylon, polyamide, Kevlar fiber, cross-linked polyethylene, polyethylene terephthalate and others, may be utilized to accomplish the expansion-limiting effect.

Consequently, claim 65 is not obvious over Steadham et al. in view of Crocker et al.

Claims 66-68 are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 66-68 under 35 U.S.C. §103(a) as being obvious over Steadham et al. (USPN 7,331,933) in view of Crocker et al. (USPN 6,120,523) is respectfully requested.

III. Anderson in view of Yang et al.

Claims 30-31 have been rejected under 35 U.S.C. §103(a) as being obvious over Anderson (USPN 6,007,517) in view of Yang et al. (US 2001/0003796).

Applicants traverse the rejection.

Claims 30 and 31 depend from claim 27 which is not obvious over Anderson in view of Yang et al. for the reasons set forth above.

It is asserted in the Office Action that "Anderson as modified by Yang et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter."

However, the combination fails to disclose or suggest all of the elements recited in independent claim 27, namely a balloon formed from a radiation curable composition and no *prima facie* case of obviousness has been established with respect to claim 27.

Claims 30 and 31 are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 30-31 under 35 U.S.C. §103(a) as being obvious over Anderson (USPN 6,007,517) in view of Yang et al. (US 2001/0003796) is respectfully requested.

Allowable Subject Matter

Claims 32-38 and 69-70 are allowed.

CONCLUSION

Claims 27, 28, 30-38 and 63-70 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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